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Means restriction for the prevention of suicide: generic protocol (Protocol)

John A, Hawton K, Okolie C, Dennis M, Price SF, Lloyd K

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[Intervention Protocol]

Means restriction for the prevention of suicide: generic protocol

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ABSTRACT

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

- To conduct a suite of reviews to assess the effectiveness of restriction of physical means of access as a method of suicide prevention. These reviews will focus on the method of suicide - jumping, colliding with a train, poisoning, hanging, using a firearm, using a sharp object, inhaling motor vehicle exhaust, drowning, and charcoal burning.

BACKGROUND

This generic protocol will provide a template for a suite of reviews assessing the effectiveness for suicide prevention of restricting access to common means of suicide. This will allow all reviews to use standard methods and collect data on the same set of outcomes, so that evidence from different reviews can be more easily compared. Interventions to be considered are those intended to restrict the means to jumping, colliding with a train, poisoning, hanging, using a firearm, using a sharp object, inhaling motor vehicle exhaust, and drowning. When possible, we will include evidence restricting the means to newly emerging methods such as charcoal burning.

This generic protocol will not become a full review but will be retained permanently as a protocol to inform the production of all means restriction reviews. Each review that is developed (and subsequently updated) on the basis of this generic protocol will include its own intervention-specific background along with more

comprehensive information related to that particular means of suicide.

Description of the condition

Suicide rates

Worldwide, suicide is recognised as a significant public health problem. It is estimated that each year around one million people will die from suicide (mortality rate, 11.4 per 100,000) (WHO 2014). Rates are said to have increased by 60% over the past 45 years, and in countries such as Japan, South Korea, China, and Taiwan, suicide is the leading cause of death among those aged 15 to 44 years (WHO 2010; WHO 2012). The World Health Organization (WHO) estimates that suicide represents 1.4% of the total global burden of disease, and that by 2020, this figure

will reach 2.4% in countries with market and former socialist economies (WHO 2008). Self-harm, which includes suicide attempts, is much more common than completed suicide and is a significant cause of morbidity.

Risk factors/causes

A variety of risk factors for suicide and suicidal behaviour are known. These include mental disorder (particularly depression and substance abuse); social, psychological, biological, and genetic factors; exposure to role models; and adverse life events (Hawton 2009; Mann 2002). Gender and age have been shown to play an important role in suicide, with higher rates reported in young men (Wasserman 2005). Men are more likely to choose violent and highly lethal methods such as firearm suicide or hanging, and women often choose poisoning or drowning, both of which are less violent and less lethal (Ajdacic-Gross 2008). However, unlike suicide, self-harm usually occurs more commonly among females (Hawton 2008). Whatever the background factors at the point when a person feels hopeless and potentially suicidal, access to the means of suicide can be decisive. Availability of means can lead from suicidal thoughts to a suicidal act, particularly when impulsive behaviour is a factor. The nature of the method chosen will influence the outcome (Yip 2012).

Definitions

A range of different terms are used for suicide and suicidal behaviour. In the context of this suite of reviews, 'suicidal behaviour' will be used for any form of deliberate or intentional self-injurious or self-poisoning behaviour with known suicidal intent. 'Suicide' will be used to refer to self-injurious or self-poisoning behaviour with a fatal outcome and known suicidal intent or where that intent was underdetermined. Self-injurious behaviour with non-suicidal intent and a non-fatal outcome will be referred to as self-harm.

Means of suicide

Despite differences between countries, three principal methods of suicide predominate worldwide (WHO 2014). These include hanging, using firearms, and poisoning by ingestion of pesticides. Jumping from a height and using other methods of poisoning (usually poisoning with drugs) are important alternate methods. Data from WHO (Ajdacic-Gross 2008) show that hanging was the predominant method of suicide in most countries included in the analysis. The highest proportions were around 90% in men and 80% in women in Eastern Europe (i.e. Estonia, Latvia, Lithuania, Poland, and Romania). Using a firearm was the most frequent method in the United States, Argentina, Switzerland, and Uruguay. In rural Latin American countries (e.g. El Salvador, Nicaragua, Peru), Asian countries (e.g. the Republic of Korea,

Thailand), and Portugal, poisoning with pesticides was a major problem, notably among women. Poisoning with drugs was common in women from Canada, the Nordic countries, and the United Kingdom. It was also a common means of male suicide in these countries. Each individual review will provide detailed information on various means of suicide.

Description of the intervention

Restricting access to common means of suicide such as firearms or toxic substances is an effective population level prevention strategy (Hawton 2005). Restricting access to means is underpinned by the concept of acute periods of risk for suicidal behaviour, for example, as might occur when a person with depression is exposed to an adverse life event. If access to means is restricted at this point, the chance of survival beyond the stage of acute risk increases. Evidence from research on near lethal suicide attempts supports the idea that, at least for a proportion of people, these attempts are an impulsive response that would not have occurred if the means had not been readily available (Hawton 2005).

It has been argued that restricting access to one method will lead to substitution with another. However, evidence suggests that restricting access to means during periods of acute risk can have an impact on an individual's likelihood of dying from suicide in the longer term. In the UK, an often used example is coal gas (Kreitman 1976). From the late 1950s to the early 1970s, domestic gas supplies changed from coal gas to non-toxic natural gas. After the Second World War, suicide rates in the UK had been increasing, and carbon monoxide poisoning via a gas oven was the most common method. With the change to natural gas, the numbers of these deaths fell. Despite a slight increase in other methods, the net effect was a large reduction in suicide deaths.

Studies have also provided evidence of near fatal attempts. A 10-year follow-up of 94 individuals who survived jumping in front of an underground (subway) train found that only nine went on to die from probable suicide. All these deaths occurred within three years and seven months of the index attempt (O'Donnell 1994).

How the intervention might work

Jumping

Most suicides by jumping occur from high-rise residential buildings (Beautrais 2007). Other common sites include bridges, cliffs, and terraces. A range of studies have demonstrated that construction of barriers and fencing at high-risk jumping sites, especially bridges, can lead to a reduction in the number of deaths (Beautrais 2001; Bennewith 2007; Cox 2013; Pelletier 2007; Pirkis 2013; Pirkis 2015).

Collision with a train

Suicide by collision with a train is a highly lethal method of death and accounts for between 1% and 12% of suicides internationally (Krysinska 2008; van Houwelingen 2010). A study evaluating the effectiveness of installing platform screen doors as a means of preventing railway suicides found a significant reduction in railway suicides following the installation of such barriers (Law 2009). Restricting public access to railway tracks can be achieved by legislation and by installation of surveillance devices.

Poisoning

By drugs

In the 1970s, a reduction in the prescribing of barbiturates was associated with a subsequent fall in suicide as a result of barbiturate poisoning (Carlsten 1996).

Legislation on the packaging of paracetamol and salicylates was introduced in the UK in September 1998; this restricted the number of tablets that could be sold in a single transaction. Some evidence suggests that this led to a reduction in the number of tablets taken in overdose (Hawton 2001), although some authors dispute this finding (Morgan 2007).

By other means

Pesticide ingestion accounts for an estimated 370,000 suicides worldwide annually; a disproportionate number occur in low- and middle-income countries (WHO 2009). Access to pesticides can be restricted by limiting sales and providing safer storage. Many high-income countries have already banned the use and export of the most lethal pesticides, and evidence from countries such as Jordan and Samoa suggests that such bans are associated with a subsequent fall in suicides (WHO 2009). Safer pesticide storage, particularly in developing countries, can be facilitated by providing locked boxes; encouraging centralised and communal storage; and educating pesticide users about the risks associated with their use and about safe storage and disposal.

Hanging

Hanging is the most common means of suicide worldwide (Gunnell 2005). Restriction of access to means of hanging is often not possible at a general population level because the most commonly used ligatures and ligature points are universally available (Sarchiapone 2011). However, in controlled environments such as hospitals and prisons, restriction of access to means of hanging can be achieved by the introduction of 'safer (ligature-free) cells', ligature-free bedding and clothes for high-risk individuals, and collapsible ligature points such as shower rails (Gunnell 2005).

Using a firearm

Among males, the proportion of suicides in which firearms are involved ranges from 0.2% in Japan to 60.6% in the United States (WHO 2009). Reducing access to firearms can be achieved through legislation, enforcement, amnesties, and collection schemes. Legislative measures may include banning certain types of firearms; licensing and registration schemes for suppliers and owners; minimum waiting periods between licensing and purchasing; safe storage checks; and background checks on and/or psychological testing of those who wish to buy them.

A systematic review of the impact of US firearms legislation on suicide rates found some studies that showed a reduction but concluded that findings were inconsistent (Hahn 2005).

Using a sharp object

Sharp objects are involved in only a small number of suicides: 2.5% in Japan and 2% in Australia (WHO 2009); however self-cutting is a common form of deliberate self-harm. Legislation can be used to limit access. In the United Kingdom, it is an offence to carry a knife or other sharp object in public without good reason.

Inhaling motor vehicle exhaust

In England and Wales, motor vehicle exhaust deaths reached a peak at the beginning of the 1990s. In 1993, new legislation required all new petrol vehicles to be fitted with catalytic converters, which reduce carbon monoxide emissions. Suicide deaths by motor vehicle exhaust subsequently declined throughout the 1990s (Brock 2003).

In the USA, rates of motor vehicle-related carbon monoxide deaths declined from 10.0 to 4.9 per million person-years over the period from 1968 to 1998 (Mott 2002). This decline was associated with enforcement of the automobile emissions standards set by the 1970 Clean Air Act; the first catalytic converters were introduced in the USA in 1975.

Drowning

Suicide by drowning ranges from 1% in the USA to 15% to 20% in Ireland (Lunetta 2014). Drowning is a very accessible method of suicide, particularly in places with easy access to water bodies. However, it is difficult to determine whether a drowning death is due to suicide or occurred by accident (Haw 2016). Continuous surveillance as well as construction of barriers on bridges could reduce the number of suicides by drowning.

Charcoal burning

Suicide by charcoal burning has emerged as a new means of suicide, particularly in Asian societies (Pan 2010). A recent study found that limiting access to charcoal in major retail outlets was effective in reducing the rate of suicide by charcoal burning (Yip 2010).

Why it is important to do this review

Several relevant reviews have been published, although not all were focused on means restriction.

A systematic review published in 2005 examined the evidence for effectiveness of specific suicide prevention interventions (Mann 2005). Review authors concluded that restricting access to lethal means was one of the few interventions for which clear evidence was available. The difficulty in directly attributing declining suicide rates to a particular means restriction in light of overall trends and factors, such as increased antidepressant use, was noted.

Evidence on the effectiveness of intentional overdose strategies was discussed in a review published in 2010 (Guo 2010). These review authors concluded that the impact of legislation to restrict access to drugs is inconsistent. They concluded that differences in impact might have resulted from variation in the methods used. They suggested that, as well as controlling for confounding factors, future studies should consider prevalence of suicidal behaviour and changes in predisposing vulnerabilities and protective factors. A systematic review published in 2011 found that several factors could influence an individual's decision regarding method of suicide, but that substantial support indicates that easy access is significant (Sarchiapone 2011). Review authors concluded that restriction of means can be particularly effective when a method is widely used, is widely available, is highly lethal, and cannot easily be substituted for by a similar method. They noted that restriction of access should be used in conjunction with other prevention approaches.

Recent reviews on interventions for self-harm in children, adolescents, and adults found little evidence from which to draw conclusions (Hawton 2015a; Hawton 2015b; Hawton 2016). Review authors recommended that further research should be undertaken to evaluate effective interventions for prevention of self-harm.

Many people who die from suicide do not seek prior treatment and can be reached only through population-based strategies. Means restriction is an important universal approach to suicide prevention and has been included within many national suicide prevention programmes. This current suite of reviews is intended to provide a systematic and exhaustive search of current available evidence to bring together findings on a variety of interventions to inform evidence-based policy and practice. In accordance with details based on the Methodological Expectations of Cochrane Intervention Reviews (MECIR) (Higgins 2016), when possible, we will include descriptions of the effects of these interventions on different population groups within the community, as well as in low- and middle-income countries.

OBJECTIVES

- To conduct a suite of reviews to assess the effectiveness of restriction of physical means of access as a method of suicide

prevention. These reviews will focus on the method of suicide - jumping, colliding with a train, poisoning, hanging, using a firearm, using a sharp object, inhaling motor vehicle exhaust, drowning, and charcoal burning.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster-randomised controlled trials, cross-over randomised controlled trials, and quasi-randomised controlled trials in our suite of reviews.

It is likely that we will find very few, or only very poor-quality, RCTs that meet our inclusion criteria. In this case, we will include the best evidence available (Petticrew 2006). We will include controlled intervention studies without randomisation, controlled before and after studies, and observational studies. If we identify very few or only very poor-quality controlled studies, we will include studies using interrupted time series design.

We will consider both published and unpublished studies.

Types of participants

Participant characteristics

We will include men and women (aged 10 and over) of all ethnicities.

Diagnosis

Participants will include individuals exhibiting suicidal behaviour. For the proposed reviews, we will define suicidal behaviour as fatal or non-fatal intentional self-harm behaviour, which includes suicide, attempted suicide, and deliberate self-harm (Silverman 2007).

Co-morbidities

Comorbidity with a mental disorder is an important factor associated with risk of suicide (Harris 1997). Participants in the suite of reviews will include individuals with a diagnosis of mental disorder, as well as those for whom a diagnosis had not been made before the suicide or attempted suicide. We will exclude studies in which participants have received a diagnosis of intellectual disability.

Setting

We will include all settings in our suite of reviews, including community and institutionalised settings such as prisons, schools, and hospitals.

Subset data

When eligible subsets of data can be retrieved, we will do so.

Types of interventions

Experimental intervention

We will undertake a suite of reviews in which we will review studies that assess the impact of restrictions on availability of, or access to, means of suicide. These include interventions intended to restrict the means to jumping, colliding with a train, poisoning, hanging, using a firearm, using a sharp object, inhaling motor vehicle exhaust, drowning, and charcoal burning. Examples of interventions to be included in each review include construction of barriers at jumping sites, installation of surveillance devices on railway tracks, legislation to restrict quantities of paracetamol and other analgesics, introduction of ligature-free cells in prisons, legislation to reduce access to firearms and sharp objects, legislation to reduce carbon monoxide emissions in motor vehicles, continuous surveillance around water bodies, and limitation of access to charcoal in major retail outlets.

We will include universal, selective, and indicated means restriction interventions. Universal interventions are those targeted at the general public or whole populations and include legislation to restrict access to means for suicidal behaviour such as ownership and storage of firearms; and installation of barriers at jumping sites. Most means restriction interventions are universal. Selective interventions are targeted at individuals or groups within a population at increased risk of suicidal behaviours and include installation of barriers on bridges close to psychiatric hospitals and use of ligature-free cells, bedding, and clothes in prisons. Indicated interventions are targeted at individuals with known suicidal behaviours and include limiting access to medication.

We will not include interventions to educate professionals (who assess or advise) or to educate the public (on storage or security of means). We also will not include interventions to restrict cognitive availability of means of suicide, for example, the impact of media portrayals, and we will not include interventions aimed at improving recognition, screening for risk, and treating or understanding the causes and risk factors of suicidal behaviour (including mental illness).

Comparator intervention

Comparator interventions or control conditions will include any other intervention or no intervention. When possible, we will include head-to-head interventions (e.g. signage on bridges vs structural changes).

Types of outcome measures

We will include in each individual review the following primary outcomes. We may include additional review-specific outcomes (primary or secondary, or both) in individual reviews.

Primary outcomes

Primary outcomes will include the following.

- Rates of suicide or attempted suicide or self-harm.
 - This outcome will be measured in two ways.
 - ◊ At population level.
 - ◊ By the specific method targeted by the means restriction initiative.
- Study dropouts.

Secondary outcomes

Secondary outcomes will include the following.

- Change in hospital admission rates for specified methods of attempted suicide or self-harm (including admissions to specialised liver units and psychiatric units).
- Cost-effectiveness of the interventions.
 - Of the two current guiding frameworks for inclusion of economic perspectives in Cochrane Reviews ([Shemilt 2013](#)), we will report this outcome using the brief economic commentary framework for incorporating economic perspectives in Cochrane Reviews, rather than performing a full systematic review of evidence from previously published economic evaluations.

Timing of outcome assessment

The intervention is expected to have an immediate effect. Outcomes will be assessed at three time points after the intervention has been introduced: immediate/short term (one to four weeks), medium term (three to 12 months), and long term (over a year).

Search methods for identification of studies

Specialised Register of the Cochrane Common Mental Disorders Group

The Cochrane Common Mental Disorders Group (CCMD) maintains a specialised register of randomised controlled trials, the CCMDCTR. This register contains over 40,000 reference records

(reports of RCTs) for depression, anxiety, bipolar disorder, eating disorders, self-harm, and other mental disorders within the scope of this Group. The CCMDCTR is in part a studies-based register, with > 50% of reference records tagged to c12,500 individually PICO-coded study records. Reports of trials for inclusion in the register are collated from (weekly) generic searches of MEDLINE, Embase, and PsycINFO; quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL); and review-specific searches of additional databases. Reports of trials are also sourced from international trials registries, drug company websites, and 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) can be found on the Group's website; an example of the core MEDLINE search is outlined in [Appendix 1](#).

Electronic searches

The CCMD Group's Information Specialist will cross-search the CCMDCTR (studies and references register) using the following search terms to find reports of randomised controlled trials (RCTs).

- #1. means near2 suicid*
- #2. (suicid* or parasuicid* or para-suicid* or self-harm* or "self harm*")
- #3. (restrict* near (access* or availab* or means or method* or prescription*))
- #4. (access* or availab* or lethal* or physical) near (means or method*)
- #5. ((eas* or secure) near access*)
- #6. ("drug packag*" or "product packag*" or (pack* near siz*))
- #7. (overdos* or "over dos*" or over-dos*) near (drug* or analgesic* or paracetamol or acetaminophen or aspirin or salicyl* or barbituat* or over-the-counter or "over the counter" or prevent*)
- #8. (poison* or self-poison* or "self poison*" or gas or gases or charcoal or burning or pesticide* or insecticide* or organophosp*)
- #9. ("exhaust fume*" or "carbon monoxide" or emission*)
- #10. (automobile* or vehicle* or car or cars)
- #11. "safe stor*" or "safe room*"
- #12. (prison* or jail* or gaol* or detention* or incarcerat* or "secure unit*")
- #13. (drowning* or suffocat* or asphyxia*)
- #14. "sharp object*" or knife or knives
- #15. (hanging or jump* or leap* or railway* or railroad* or subway or "sub way" or metro or underground or "tall building*" or "car park*" or carpark* or high-rise* or "high rise*" or architectur* or "environment design" or bridge* or cliff*)
- #16. (firearm* or "fire arm*" or fire-arm* or gun or guns* or hand-gun* or "hand-gun*" or hand-gun*)
- #17. (structural or physical) NEAR (intervention or barrier)
- #18. (barrier* or rail* or net or nets) and (safe* or prevent*)
- #19. (#1 or (#2 and (#3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18)))

The Information Specialist will search the Cochrane Library, including the Cochrane Central Register of Controlled Trials (CENTRAL), for additional controlled trials (RCTs, controlled clinical trials (CCTs)) using a similar set of terms ([Appendix 2](#)).

We will conduct complementary searches of the following bibliographic databases (for condition + intervention only, we will apply no study design filters). We will apply relevant subject headings (controlled vocabularies) and search syntax to each resource as appropriate.

- Ovid MEDLINE (1946 to date); search strategy listed in [Appendix 3](#).
- Ovid PsycINFO (all years).
- Ovid Embase (1980 to date).
- Web of Science Core Collection: citation Indexes (all years).

We will search International trial registries via the World Health Organization trials portal ([ICTRP](#)) and [ClinicalTrials.gov](#) to identify unpublished and ongoing studies.

We will apply no restriction on date, language, or publication status to these searches.

Searching other resources

Grey literature

We will search the following sources of grey literature.

- Networked Digital Library of Theses and Dissertations (NDLTD).
- ProQuest Dissertations and Theses database.
- National Guideline Clearing House (<http://guideline.gov/>).
- OpenGrey (<http://www.opengrey.eu/>).
- Google Scholar.

The search strategy will be broad and will be designed to capture a range of references.

Reference lists

In addition to the searches outlined above, we will check the reference lists of all included studies and relevant systematic reviews to identify additional studies missed during the original electronic searches (e.g. unpublished or in-press citations). We will also conduct a cited reference search on the Web of Science.

Correspondence

We will contact trialists and subject experts to ask for information on unpublished and ongoing studies, or to request additional trial data.

Data collection and analysis

Selection of studies

We will screen all reports and publications identified as the result of the search for inclusion in the reviews. Two review authors (CO, AJ) will do this independently for all reviews. Upon review of titles and abstracts, we will code these reports as 'retrieve' (eligible, potentially eligible, or unclear) or 'do not retrieve'. We will obtain the full-text report/publication for each one coded 'retrieve'. Two review authors (CO, AJ) will review the full texts to independently screen and identify studies for inclusion. We will record the reasons for exclusion of ineligible studies. Review authors will resolve disagreements through discussion or, if required, through consultation with a third review author (KL, KH). We will exclude all duplicate records. When we find multiple reports of the same study, we will collate them to ensure that each study rather than each report/publication is the unit of interest in the review. We will record the selection process in sufficient detail to allow us to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors (CO, AJ) or other named authors where necessary will extract study characteristics and outcome data and will enter this information into a data collection form that has been piloted specifically for this suite of reviews.

One review author will enter details of each included study into the Cochrane software Review Manager 5.3 (RevMan 2014), and a second author will review the data. We will record data on the following (Armstrong 2007).

- Methods: study design, total duration of study, details of any 'run-in' period, number of study centres and locations, study setting, withdrawals of the intervention, and dates of the study.
- Participants: N, mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria, and exclusion criteria.
- Interventions: intervention, comparison.
- Outcomes: primary and secondary outcomes specified and collected, time points reported.
 - Statistical analysis.
 - Results.
 - Limitations.
 - Notes: funding for trial and notable conflicts of interest of trial authors.

We will separate eligible studies into the following categories for purposes of data extraction.

- Jumping (to include buildings and bridges).
- Collision with a train.
- Suicide on roads.
- Poisoning.

- Hanging.
- Use of a firearm.
- Use of a sharp object.
- Motor vehicle exhaust.
- Drowning.
- Charcoal burning.

When data are not reported in a useable way, we will note this in the 'Characteristics of included studies' table. We will resolve disagreements first by consensus and when this fails by consultation with a third review author (KL or KH). One review author (CO) will be nominated as the person who will transfer data into Review Manager (RevMan 2014). Data entered will be double-checked for accuracy by comparing data presented in the systematic review versus data provided in the study reports. Additionally, a second review author (AJ) will spot-check study characteristics for accuracy against the trial report.

Main comparisons

For each review, we will conduct the following main comparisons. We will stratify graphs according to type of intervention.

- Universal intervention versus no intervention.
- Universal intervention versus any other intervention.
- Selective intervention versus no intervention.
- Selective intervention versus any other intervention.
- Indicated intervention versus no intervention.
- Indicated intervention versus any other intervention.

Assessment of risk of bias in included studies

Two review authors (CO, AJ) will independently assess risk of bias for each study included in the proposed suite of reviews. We hypothesise that our included studies will consist of randomised and non-randomised studies; therefore we will base our criteria on Cochrane's tool for assessing risk of bias in RCTs (Higgins 2011) and Cochrane's risk of bias tool for non-randomised studies (Sterne 2016). We will resolve disagreements in the first instance by consensus and when this fails through involvement of a third review author (KL, KH).

For randomised trials, we will base our assessment on the following domains.

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- Other bias.

We will judge each potential source of bias as having high, low, or unclear risk and will provide a supporting quotation from the study report together with a justification for our judgement in the

'Risk of bias' table. We will summarise risk of bias judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes when necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient-reported pain scale). When information on risk of bias is related to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

When considering treatment effects, we will take into account the risk of bias for studies that contribute to that outcome.

Assessment of methodological quality of included studies

Two review authors (CO, AJ) will independently appraise studies. We will refer to a third review author (KL, KH) any disagreements that cannot be resolved. When necessary, we will contact study authors for further information.

In addition to using the Cochrane 'Risk of Bias' tool, we plan to use the 'Risk of Bias in Non-randomised Studies of Interventions (ROBINS-I)' tool to assess risk of bias for each included study (Sterne 2016). This new tool can be used to evaluate risk of bias in estimates of the comparative effectiveness of interventions from studies that did not use randomisation to allocate units to comparison groups (Sterne 2016). This tool assesses studies on seven domains of bias.

- Confounding.
- Selection bias.
- Bias in measurement classification of interventions.
- Bias due to deviation from intended interventions.
- Bias due to missing data.
- Bias in measurement of outcomes.
- Bias in selection of the reported result.

Application of assessment criteria will be piloted to ensure that criteria can be applied consistently. We will assess inter-rater reliability using the kappa statistic. We will resolve disagreements on data extraction by consensus discussion, following review by a third assessor.

Measures of treatment effect

Dichotomous data

We will analyse dichotomous data as risk ratios (RRs) with 95% confidence intervals (CIs).

Continuous data

We will analyse continuous data as mean differences (MDs) if trials measure outcomes the same way. We will use standardised mean differences (SMDs) to combine trials that measure the same

outcome but use different methods. We will enter data presented as a scale with a consistent direction of effect.

We will undertake meta-analyses only when this is meaningful (i.e. when treatments, participants, and the underlying clinical question are similar enough for pooling to make sense).

We will narratively describe skewed data reported as medians and interquartile ranges.

Unit of analysis issues

Cluster-randomised trials

If identified, we will include in analyses cluster-randomised trials that meet all eligibility criteria along with individually randomised trials. We will adjust sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) based on an estimate of the intracluster correlation coefficient (ICC) derived from that trial (if available), from a similar trial, or from a study of a similar population. If we use ICCs from other sources, we will report this and will undertake sensitivity analyses to investigate the effect of variation in ICCs. If we identify both cluster-randomised and individually randomised trials, we will plan to synthesise any relevant information. We will consider combining the results from both types of trials if we note little heterogeneity between study design and if we consider interaction between the effect of the intervention and the choice of randomisation unit to be unlikely. We will acknowledge heterogeneity in the randomisation unit and will perform a sensitivity analysis to investigate effects of the randomisation unit. We will take this approach only if a cluster RCT has been incorrectly analysed, as though the unit of allocation had been randomised at the level of the individual participant.

Cross-over trials

If we identify any cross-over trials, we will consider the first period of measurement only and will analyse study results together with those derived from parallel-group studies.

Studies with multiple treatment groups

When multiple trial arms are reported in a single trial, we will combine the arms to create a single pair-wise comparison when possible (Higgins 2011). If this is not possible, we will use alternate methods set out in the *Cochrane Handbook for Systematic Reviews of Interventions* to avoid double-counting of study participants (Higgins 2011).

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, review authors will carry out analyses, as far as possible, on an intention-to-treat basis (i.e. they will attempt to include in analyses all participants randomised to each group and will analyse all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention). The denominator for each outcome in each trial will be the number randomised minus the number of participants whose outcomes are known to be missing.

When important data or information about the study design is missing, we will contact investigators or study sponsors to verify key study characteristics and to obtain missing numerical outcome data when possible (e.g. when a study is identified as abstract only). We will document all correspondence with trialists and will report in the review which trialists responded to our requests.

Assessment of heterogeneity

Review authors will assess heterogeneity by using appropriate statistical tests. We will use the I^2 statistic to assess heterogeneity between trials (Higgins 2011). Thresholds for interpreting I^2 are as follows.

- 0% to 40%: might not be important.
- 30% to 60%: may represent moderate heterogeneity.
- 50% to 90%: may represent substantial heterogeneity.
- 75% to 100%: considerable heterogeneity.

If we detect substantial heterogeneity, we will explore possible causes and will perform subgroup analyses for main outcomes. We will use a random-effects model to allow for expected heterogeneity. Effect estimates will be weighted by the inverse of their variance, with greater weight given to larger trials. We could carry out a meta-analysis of similar interventions to provide an indication of the direction if not the size of any effect.

We will give consideration to meta-analysis of RCTs, quasi-RCTs, and studies of other designs. When not appropriate, we will summarise studies in tables and by narrative synthesis.

Assessment of reporting biases

If 10 or more studies report the same outcome of interest, we will generate funnel plots to investigate the relationship between study power and effect size. We will consider randomised and non-randomised studies separately. An asymmetrical plot may indicate biases such as publication bias, poor quality of smaller studies, or true differences related to smaller studies (e.g. different populations). We will explore possible reasons for any asymmetry detected (Egger 1997).

Data synthesis

We will carry out statistical analysis using Review Manager software (RevMan 2014). When more than one study examines the same intervention and we judge study populations and methods as being sufficiently similar, we will conduct a meta-analysis to provide an overall estimate of treatment effect. Because of the varied nature of the interventions reviewed (including interventions and settings), we will use a random-effects meta-analysis model when combining data. We will not combine results from RCTs and non-RCTs in a meta-analysis, nor will we pool estimates from non-randomised studies with those from studies of different designs. When we deem that meta-analysis is inappropriate owing to significant heterogeneity, we will provide a narrative synthesis of results.

Subgroup analysis and investigation of heterogeneity

Suicidal behaviour is strongly associated with a history of self-harm or mental disorder. Effect sizes in these high-risk groups are generally higher than in the general population. Therefore, when data are available, we will perform the following subgroup analyses for all reviews.

- Comorbidity versus no comorbidity.
- History of self-harm versus no known history of self-harm.
- Diagnosis of mental disorder versus no known history of mental disorder.
- Adults versus people younger than 18 years.

We will use only primary outcomes in the subgroup analysis. For random-effects meta-analyses, we will examine differences between subgroups by visually inspecting the subgroup's confidence intervals; non-overlapping CIs suggest a statistically significant difference in treatment effect between subgroups. We will provide totals and subtotals for subgroup analyses. We will assess subgroup differences by using the interaction tests available in RevMan (RevMan 2014).

When we find evidence of inconsistency between subgroups, we will report this in the text and will present results by quoting the Chi^2 statistic and the P value, along with the interaction I^2 statistic value. We will explore subgroup differences as a means of exploring heterogeneity.

Sensitivity analysis

We will conduct sensitivity analyses to examine the effects of excluding from the analysis studies judged to be at high risk of bias (e.g. by excluding studies with high or unclear risk of selection bias (random sequence generation and allocation concealment), incomplete outcome data, substantial levels of heterogeneity). If exclusion of these studies does not substantially alter the direction of effect or the precision of effect estimates, we will include all relevant data from these studies in the analysis. We will consider randomised and non-randomised studies separately.

'Summary of findings' table

We will summarise the body of evidence for all critical and important outcomes using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. The GRADE approach defines the quality of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest (Schünemann 2011). We will summarise the assessment in a 'Summary of findings' table created with GRADEpro software. We shall assess the long-term (over one year) quality of the body of evidence related to the following outcomes.

- Rates of suicide or attempted suicide (both at the population level and by the specific method targeted by the means restriction initiative).
- Change in hospital admission rates for specified methods of attempted suicide (including admissions to specialised liver units and psychiatric units).
- Cost-effectiveness of interventions.

- Study dropouts.

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Disclaimer

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* Indicates the major publication for the study

APPENDICES

Appendix 1. Cochrane Specialised Register - core MEDLINE search strategy

Core search strategy used to inform the Cochrane Common Mental Disorders Group's Specialised Register: OVID MEDLINE

A weekly search alert based on condition + RCT filter only

1. *[MeSH Headings]:*

eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or 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/

2. *[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).ti,kf.

3. *[RCT filter]:*

(controlled clinical trial.pt. or randomized 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 subtitut* 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 randomized 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.)

4. (1 and 2 and 3)

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

Similar weekly search alerts are also conducted on OVID EMBASE and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource

Appendix 2. The Cochrane Library search

- #1. "means restriction" or (means near/2 suicid*)
- #2. (suicid* or parasuicid* or para-suicid* or "self harm*" or self-harm*)
- #3. MeSH descriptor: [SUICIDE] explode all trees
- #4. MeSH descriptor: [SELF-INJURIOUS BEHAVIOR] this term only
- #5. (#2 or #3 or #4)
- #6. (restrict* near (access* or availab* or means or method* or prescription*))
- #7. (access* or availab* or lethal* or physical) near/2 (means or method*)
- #8. ("drug packag*" or "product packag*" or (pack* near siz*))
- #9. "over the counter"
- #10. MeSH descriptor: [PRODUCT PACKAGING] this term only

- #11. MeSH descriptor: [DRUG PACKAGING] this term only
- #12. MeSH descriptor: [LEGISLATION, DRUG] this term only
- #13. MeSH descriptor: [ACETAMINOPHEN] this term only and with qualifier(s): [Supply & distribution - SD]
- #14. (overdos* or over dos* or over-dos*) near/2 (drug* or analgesic* or paracetamol or acetaminophen or aspirin or salicyl* or barbituat* and prevent*)
- #15. MeSH descriptor: [DRUG OVERDOSE] this term only and with qualifier(s): [Prevention & control - PC]
- #16. (poison* or self-poison* or "self poison*" or gas or gases or charcoal or burning or pesticide* or insecticide* or organophosp*)
- #17. ("exhaust fume*" or "carbon monoxide" or emission*)
- #18.(automobile* or vehicle* or car or cars)
- #19. MeSH descriptor: [GAS POISONING] explode all trees
- #20. MeSH descriptor: [ORGANOPHOSPHATE POISONING] this term only
- #21. MeSH descriptor: [PESTICIDES] explode all trees
- #22. MeSH descriptor: [AGRICULTURE] this term only
- #23. MeSH descriptor: [RURAL POPULATION] this term only
- #24. MeSH descriptor: [POISONING] this term only
- #25. MeSH descriptor: [CHARCOAL] this term only
- #26. MeSH descriptor: [VEHICLE EMISSIONS] this term only and with qualifier(s): [Legislation & jurisprudence - LJ, Poisoning - PO]
- #27. "safe* stor*" or "safe* room*"
- #28. MeSH descriptor: [ASPHYXIA] this term only
- #29. MeSH descriptor: [DROWNING] this term only
- #30. (asphyxia* or suffocat* or drowning*)
- #31. (prison* or jail* or gaol* or detention* or incarcerat* or "secure unit*")
- #32. MeSH descriptor: [PRISONS] explode all trees
- #33. "sharp object*" or knife or knives
- #33. MeSH descriptor: [WOUNDS and INJURIES] this term only and with qualifier(s): [Prevention & control - PC]
- #34. (hanging or jump* or leap* or railway* or railroad* or subway or "sub way" or metro or underground or "tall building*" or "car park*" or carpark* or high-rise* or "high rise*" or architectur* or bridge* or cliff*)
- #35. (barrier* or rail* or net or nets) near (safe* or prevent*)
- #36. (structural or physical) next (intervention or barrier)
- #37. MeSH descriptor: [ENVIRONMENT DESIGN] this term only
- #38. MeSH descriptor: [ARCHITECTURAL ACCESSIBILITY] this term only
- #39. (firearm* or "fire arm*" or fire-arm* or gun or guns* or handgun* or "hand-gun*" or hand-gun*)
- #40. MeSH descriptor: [FIREARMS] this term only
- #41. MeSH descriptor: [URBAN POPULATION] this term only
- #42. MeSH descriptor: [PUBLIC POLICY] this term only
- #43. MeSH descriptor: [MASS MEDIA] this term only
- #44. (#1 or (#5 and (#6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43)))
- #45. SR-DEPRESSN or HS-DEPRESSN
- #46. (#42 not #43)

Appendix 3. Ovid MEDLINE search

A precision maximizing search of MEDLINE will be conducted (no study design filters will be applied)

1. SUICIDE/ or SUICIDAL IDEATION/ or SUICIDE, ATTEMPTED/
2. SELF-INJURIOUS BEHAVIOR/
3. (suicid* or parasuicid* or para suicid*).tw.
4. or/1-3
5. (restrict* adj3 (access or mean*1 or method*1)).tw.
6. (lethal* adj3 (mean*1 or method*1)).tw.
7. DRUG PACKAGING/
8. LEGISLATION, DRUG/
9. ACETAMINOPHEN/sd [Supply & Distribution]
10. exp ANALGESICS/lj, sd [Legislation & Jurisprudence, Supply & Distribution]
11. VEHICLE EMISSIONS/lj, po [Legislation & Jurisprudence, Poisoning]
12. "WOUNDS AND INJURIES"/lj, pc [Legislation & Jurisprudence, Prevention & Control]
13. ENVIRONMENT DESIGN/
14. or/4-13
15. ARCHITECTURAL ACCESSIBILITY/
16. RAILROADS/
17. DRUG OVERDOSE/
18. (poison* or paracetamol or acetaminaphen or analgesic* or over-the-counter).ti.
19. FIREARMS/
20. WOUNDS, GUNSHOT/
21. (firearm* or gun or guns or handgun* or hand gun*).ti.
22. exp PESTICIDES/
23. POISONING/ or GAS POISONING/ or CARBON MONOXIDE POISONING/ or ORGANOPHOSPHATE POISONING/
24. CHARCOAL/
25. (pesticide* or charcoal or rural*).ti.
26. AGRICULTURE/
27. RURAL POPULATION/
28. URBAN POPULATION/
29. PRISONS/
30. (hanging or jump* or leap* or bridge*1 or barrier*1 or net*1 or railway* or railroad* or subway).ti.
31. ASPHYXIA/
32. DROWNING/
33. (asphyxia* or suffocat* or drowning*).ti.
34. PUBLIC POLICY/
35. MASS MEDIA/
36. or/15-35
37. prevention & control.fs.
38. ((prevent* and suicid*) or ((preventive or prevention) and (intervention* or program*)) or (prevention and control)).mp.
39. SURVIVAL ANALYSIS/ or SURVIVAL RATE/
40. or/37-39
41. 36 and 40
42. (4 and (14 or 41))

CONTRIBUTIONS OF AUTHORS

AJ conceived the concept for the suite of reviews.

AJ, MD, SP, and KL developed the basis for the protocol.

AJ and CO were involved in writing the protocol.

AJ and CO will take part in searching, identifying and assessing studies, extracting data, and performing analyses.

MD, SP, and KL provided general advice on the protocol.

DECLARATIONS OF INTEREST

KL and AJ are co-directors the Cochrane Satellite for Suicide and Self-Harm portion of the Cochrane Common Mental Disorders Group. SP and CO are members.

KH has been involved in trials and studies related to means restriction of paracetamol/aspirin and locked boxes in low- and middle-income countries, and will play no part in any decisions related to any of his studies.

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External sources

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